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13.2

Exposure Control Plan: Working Safely with Blood and Bloodborne Pathogens

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Recommended for approval by the ES&H Working Group

Approved by: Robert W. Kuckuck
Deputy Director for Operations

New document or new requirements

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13.2

**Exposure Control Plan:
Working Safely with Blood and Bloodborne Pathogens***

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Exposure Control Plan: Working Safely with Blood and Bloodborne Pathogens

1.0 Introduction

The Occupational Safety and Health Administration (OSHA) issued 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens," to protect workers from anticipated exposures to bloodborne pathogens that include human bodily fluids potentially contaminated with the human immunodeficiency virus (HIV), hepatitis C virus (HCV), the hepatitis B virus (HBV), or other bloodborne pathogens.

This document is LLNL's Exposure Control Plan, which outlines strategies and specific safe work practices for workers who anticipate working with human blood or bodily fluids. In general, the requirements in this document apply to all areas at LLNL where occupational exposures to human blood, blood components, and other sources of bloodborne pathogens are anticipated.

The requirements in this document apply to

- All University of California (UC) Laboratory workers.
- Hosted visitors, students, participating guests, contract laborers, and supplemental personnel.
- Workers of other firms working at locations where LLNL has management control of specific biohazards.
- Workers who volunteer to provide emergency first aid under a facility's Self-help Plan.

However, these requirements DO NOT apply to non-LLNL personnel working at LLNL locations where specific biohazards exist but where LLNL has no management control.

2.0 Hazards

Exposure to bloodborne pathogens may occur in occupational settings where there is contact with materials potentially contaminated with human bodily fluids (e.g., blood) or bloodborne pathogens. Individuals at risk shall take steps to protect themselves from exposure. The risk of infection following contact with contaminated equipment or blood varies depending on the type of infectious agent and the extent of actual exposure to the individual.

The likelihood of an infection occurring from an accidental bloodborne exposure depends on a number of factors, including

- The probability that the material (e.g., blood) was contaminated.
- The health status of the individual.
- The efficiency of the transmission

The source of material involved in an accidental bloodborne exposure may be tested for specific bloodborne contaminants such as HIV, HBV, and HCV. Appropriate medical evaluation or treatment shall be sought whenever an exposure occurs or is thought to have occurred.

The individual's health status plays a key factor in how an individual responds to an exposure. Pre-existing diseases, the use of medication, compromised immunity, and pregnancy are factors to consider when determining how the individual may respond to an exposure.

The efficiency of the transmission depends upon the type of wound, severity of exposure, infectious dose, routes of infection, and the ability of the organism to produce disease. Listed in Table 1 are human bloodborne pathogens, morbidity and mortality information, incubation periods, and sources. The specimen sources are from humans unless otherwise specified, i.e. rodents.

3.0 Controls for Working with Blood and Bloodborne Pathogens

The controls required for work with human blood and bloodborne pathogens include:

- Performing an environment, safety, and health (ES&H) evaluation as part of the hazard-reduction process to determine the workers who are at risk.
- Establishing engineered controls, administrative and procedural controls, and safe work practices for activities involving the handling of blood and bloodborne pathogens.
- Enrolling workers in the Health Services Department medical surveillance and immunization programs (see Sections 3.2.3 and 3.2.7 of this document).
- Training workers about the hazards that can be introduced into the workplace.

Table 1. List of Bloodborne Pathogens.^{a,b,c}

Disease/Agent(s)	Common Names	Risk	Incubation	Sources
Serum Hepatitis/Hepatitis B Virus	Hepatitis B (42 nm), Hepadnavirus dsDNA	6–10% infection 1–2% fatal	11 weeks	Blood, semen, saliva, cerebral spinal fluid
Transfusion Hepatitis/Hepatitis C Virus	Hepatitis C, Non A, Non B (40–60 nm), Flaviviridae (ss RNA)	0.5–1% fatal	7 weeks	Blood, serum
AIDS: Retroviridae(100 nm) (Oncornavirus - RNA)	HIV–1, LAV (formally HTLV III)	< 0.5% infection, 100% fatal	Adults: 8 years Infants: 2 years	Blood, serum, saliva, tears, urine, breast milk, amniotic fluid, cerebral spinal fluid
	HIV-2 (West Africa) HTLV IV	<8.9% infection 100% fatal	Unknown	Blood, serum, saliva, tears, urine, breast milk, amniotic fluid, cerebral spinal fluid
Leukemia/Lymphomas Human T-Lymphotropic Virus (HTLV)	Retroviridae (Oncornavirus 100 nm), HTLV I	18–49% infection	Unknown	Blood
	HTLV II	52% Infection	Unknown	Blood
	HTLV V	Unknown	Unknown	Blood
Transmissible spongiform encephalopathies (CJD)	Creutzfeldt-Jakob Disease	30 cases per million	10–15 yrs.	Neurological and brain tissues, corneal spinal cord, transplant tissues
Kuru (50–300 μ m)	Kuru Disease	Unknown	10–30 yrs.	Spinal cord, brain
Hemorrhagic fever: Marburg virus	Filovirus-ss RNA: (900 \times 80 nm) MBG	22% fatal	4–16 days	Rodents, bodily fluids
Ebola virus	EBO	53–88% fatal		Rodents, bodily fluids
Argentine hemorrhagic fever	Junin virus (arenavirus: ss RNA-130 \times 20 nm)	15% fatal	7–14 days	Rodents, bodily fluids, cerebral spinal fluid
Bolivian hemorrhagic fever	Machupo virus (ss RNA) Arenavirus 130 \times 20 nm	18% fatal	7–14 days	Rodents, bodily fluids
Venereal syphilis/ <i>Treponema pallidum</i>	Bacterial spirochete (6–15 \times 0.1–0.2 μ m)	14.6 per 100,000 cases	10–90 days	Bodily fluids

^a Hunt, D.L., "Human Immunodeficiency Virus Type 1 and Other Bloodborne Pathogens," *Laboratory Safety: Principles and Practices*, 2nd ed, Fleming, Richardson, Tulis, Vesley, Eds. (American Society of Microbiology, 1995) pp. 33–66.

^b Jahrling, Peter, "Marburg Virus, Ebola Virus, and the Arenaviruses," *Manual of Clinical Microbiology*, 4th ed, Lennette, Balows, Hausler, and Shadomy, Eds. (American Society of Microbiology, 1985) pp. 796–804.

^c Swenson, P.D., "Hepatitis Viruses," *Manual of Clinical Microbiology*, 5th ed, Balows, Hausler, Herman, Isenberg and Shadomy, Eds. (American Society of Microbiology, 1991) pp. 959–983.

Research laboratories and production facilities that are engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV shall adhere to specific OSHA guidelines and work practices (e.g., work in biological safety 2

containment facilities with biological safety 3 work practices). Appendix A of this document contains additional precautions and safe work practices that do not apply to clinical or diagnostic laboratories.

3.1 Engineered Controls

Engineered controls and safe work practices are the primary means of eliminating or minimizing the risk of occupational exposure when handling blood or other potentially infectious materials. Engineered controls for research laboratories include but are not limited to mechanical aids, safety syringes, dead air boxes, sharps disposal containers, laboratory-type fumehoods, biological safety cabinets, and negative air-flow units. These units are used to isolate or remove bloodborne hazards from laboratory workplaces to minimize or reduce the potential of bloodborne exposure. Engineered controls for non-research laboratory operations vary from site to site and are not discussed in this document. Consult your ES&H Team for further evaluation and recommendations.

3.1.1 Sharps Disposal Containers

Sharps disposal containers are used to dispose of contaminated sharps (i.e., needles, scalpels, broken glass, broken capillary tubes) to minimize the potential for accidental skin penetrations. These containers

- Are rigid, puncture-resistant containers that, when sealed, are leak resistant and difficult to open.
- Shall be red in color, have a biohazard label, be accessible to workers, and be located as close as feasible to the immediate area where sharps are used.
- Shall remain upright throughout use and be replaced routinely.
- Shall not be overfilled so as to present a hazard.

Prior to removal from the area of use, containers of contaminated sharps shall be closed immediately or placed in a secondary container to prevent accidental release of the contents. Secondary containers shall be closable and constructed to contain all the contents and prevent leakage during handling, storage, transport, or shipping. These containers shall also have a biohazard label.

3.1.2 Biological Safety Cabinets

Class I, Class II, and Class III biological safety cabinets (defined in Appendix G and discussed in Document 13.1, "Biological Controls and Operations," in the *ES&H Manual*) serve as primary containment devices for operations involving potential splashes, spills,

or aerosolization of biohazardous materials. These cabinets shall be tested after each installation, after each relocation, and at least annually thereafter to ensure the effectiveness of the unit.

3.2 Administrative Controls

Safe work practices are different for each task and are developed based on the severity of the hazards involved. Work with human bodily fluids shall be performed using the Biosafety Level 2 or higher containment work practices outlined by the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) in *Biosafety in the Microbiological and Biomedical Laboratories*, 4th ed. (U.S. Department of Health and Human Services, Centers of Disease Control and the National Institutes of Health, Washington, DC, May 1999). Universal precautions can be found in Appendix B. General work practices, personal hygiene, general housekeeping practices, and transportation requirements can be found in Document 13.1.

3.2.1 Exposure Control Plan

Title 29 CFR Part 1910.1030 is a performance-based standard that requires employers to

- Develop an exposure control plan to identify workers by *job classification* with potential occupational exposure, and all workers by *job classification and task/procedures* with potential occupational exposure.
- Train all occupationally exposed workers on the risk of exposure and methods to reduce exposures at the time of initial assignment and annually thereafter.
- Maintain worker training records and medical evaluations.
- Use warning labels and signs to communicate hazards.
- Implement procedures to ensure that workers safely handle sharps, specimens, contaminated laundry, and waste.
- Make available the HBV vaccine at no cost to affected workers. (Appendix C gives a brief synopsis of the effectiveness of this vaccine.)
- Provide medical evaluations and follow-up after exposure incidents.
- Evaluate exposure incidents.
- Provide personal protective clothing and equipment to workers who work in areas where exposure to bloodborne pathogens, including HIV and HBV, is possible. (Appendix D provides summary information on HIV and HBV in the workplace.)

- Institute additional precautions for HIV and HBV research and production facilities, if applicable.
- Review and update the Exposure Control Plan at least annually to reflect changes in the tasks and procedures affecting exposure.

Precautions and safe work practices that are specific to each job classification and that should be included in individual Exposure Control Plans can be found in Appendices B, E and F. Work practices for a specific task may also be covered in a specific Facility Safety Plan (FSP) or Operational Safety Plan (OSP).

OSHA's Model Exposure Control Plan is in Appendix D of CPL 2-2.44D, "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens and can be found at the following Internet address:

http://www.osha-slc.gov/OshDoc/Directive_data/.

3.2.2 Performing an ES&H Evaluation

With assistance from ES&H Team personnel, the Responsible Individual shall conduct an ES&H evaluation using an Integration Work Sheet (IWS) for each activity where worker exposure to human blood or other potentially infectious materials is possible. This evaluation shall identify the workers who are at risk and all health hazards and environmental concerns, and shall determine the controls that are necessary to reduce hazards to acceptable levels and comply with accepted orders and regulations.

3.2.3 Worker Exposure Determination

LLNL has determined the following job classifications as having a potential for blood or bloodborne pathogens exposure:

- Health care providers with patient care responsibilities in the Health Services Department.
- Laboratory (i.e., clinical, research, and bioassay) personnel who work with bloodborne pathogens, human blood, or other potentially contaminated human bodily fluids.
- Fire and rescue paramedic personnel who have patient contact or who are required to clean up spills.
- Sworn peace officers and the Range Master.
- Personnel (e.g., health and safety technicians) required to clean up/handle blood.
- Medical waste handlers who may be in contact with blood or bodily fluids.

3.2.4 Handling of Sharps

Contaminated needles cannot be recapped or removed from disposable syringes by hand (i.e., using a two-handed technique) unless recapping is required during a specific medical procedure or there is no feasible alternative (e.g., blood-gas analysis). Needles shall be recapped or removed with a mechanical device that protects the hand or by a safe, one-handed recapping technique. Bending, shearing, or breaking of contaminated needles is prohibited.

Employees using disposable syringes as part of a prescribed medical treatment plan by their personal physician are asked to safely contain their syringes and needles (e.g. coffee can with lid) and take them home to dispose of as part of their household trash.

3.2.5 Spill Clean-Up

Emergency response and spill cleanup procedures are discussed in Document 13.1, and Document 22.2, "Environmental Emergency Response," in the *ES&H Manual*. All waste shall be handled as medical waste and disposed of in accordance with local, state, and federal medical waste regulations. Contact your ES&H Team for further information.

3.2.6 Signs and Labels

Labels and signs shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials, and other containers used to store, transport, or ship blood or other potentially infectious materials and contaminated equipment. Biohazard labels shall be predominantly fluorescent orange or orange-red with lettering or symbols in a contrasting color. Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other methods that prevent loss or unintentional removal. Red bags or red containers may be substituted for labels.

3.2.7 Immunization Post-Exposure and Follow-up Programs

Hepatitis B Immunization Program. Workers who are identified in Section 3.2.3 as being at risk for exposure to blood or bloodborne pathogens shall be offered participation in the Hepatitis B Immunization Program administered by the Health Services Department. The Responsible Individual shall communicate to the payroll supervisor any concerns about the potential exposure to bloodborne pathogens. The payroll supervisor shall notify the Health Services Department so that at-risk workers can be screened for eligibility to enroll in these programs. It is the responsibility of the payroll supervisor to ensure that enrollment by eligible workers is completed.

All information obtained by the Health Services Department, including a declination statement, is confidential and is kept in the workers medical records. The Health Services Department will communicate to the payroll supervisor whether or not the requirements of the law have been met.

The Health Services Department also provides counseling, prescreening blood tests, and the HBV immunization series in the treatment area of Building 663 and at the satellite clinic at Site 300.

Post-Exposure and Follow-up Program. The Post-Exposure and Follow-up Programs administered by the Health Services Department are available to workers who have been exposed to human blood, blood components, and other sources of bloodborne pathogens. The Health Services and Hazards Control Departments work collaboratively to evaluate workplaces and recommend actions that will reduce the risk of exposures. Contact the Health Services Department for more information about these programs.

3.2.8 Training

Workers who may handle blood or other potentially infectious materials shall be trained at the time of initial assignment and annually thereafter. General training (Course HS4400, "Working with Blood and Bloodborne Pathogens") and annual retraining (Course HS4400R) are offered through the Hazards Control Department. The following topics are covered in these courses:

- Explanation of the contents of 29 CFR 1910.1030.
- Epidemiology, symptoms, and the mode of transmission of bloodborne diseases.
- Exposure control plans.
- Tasks where exposure is possible.
- Uses and limitations of various controls.
- Selection and use of personal protective equipment.
- Hepatitis B Immunization Program.
- Emergency procedures.
- Post-exposure procedures.
- Warning signs and labels.
- Additional requirements for research and production laboratories.
- Recordkeeping.

A record of courses completed by workers is maintained in the Laboratory Training and Information Network (LTRAIN). As a requirement of 29 CFR 1910.1030, all training records shall be maintained for at least three years from the date of training. Job-specific training is the responsibility of the responsible individual/work supervisor.

3.3 Personal Protective Equipment

3.3.1 General

If a hazard still exists after implementing engineered controls, personal protective equipment shall be used as supplemental protection. The key elements in the selection of effective and appropriate protection are identifying and understanding workplace hazards and matching the needed PPE to each workplace hazard. It is the Responsible Individual's responsibility to make sure that a worker uses the appropriate PPE whenever there is a potential for exposure to blood, bloodborne pathogens, or other potentially infectious materials.

The type of protection selected shall be based on the degree of anticipated exposure. Gloves, gowns, face shields, masks, and protective eye wear are provided when necessary and shall be worn only in occupational exposure situations; they shall not be worn outside designated work areas. When gross contamination of the head, body, or feet is anticipated, the use of surgical caps, laboratory coats, hoods, and shoe covers is required. Sandal-type shoes and other open-type shoes are prohibited. Socks alone do not provide adequate protection from gross contamination; therefore, close-toed shoes shall be worn at all times. For more information, see Document 11.1, "Personal Protective Equipment," in the *ES&H Manual*.

3.3.2 Gloves

Gloves are required when there is a reasonable likelihood of hand contact with blood or other potentially infectious materials or when workers have cuts, scratches, or other breaks in their skin. Hypoallergenic gloves, glove liners, and powderless gloves are available. Disposable (i.e., single use) gloves that become contaminated, torn, or punctured shall be replaced; and hands shall be washed upon removing the gloves. "Double gloving" (i.e., the use of two pairs of gloves) may be required for additional protection or to reduce the frequency of required hand washing. Disposable gloves shall not be washed or decontaminated for reuse.

Utility gloves that are designed for more than one use may be decontaminated for reuse if the integrity of the gloves is not compromised. Utility gloves that are cracked, peeling, torn or punctured, or that exhibit signs of deterioration, shall be discarded. For more information on gloves, see

<http://ctmsds.llnl.gov:1650/livehtml/ChemSafety/chemsafety.html>

3.3.3 Face and Eye Protection

Face and eye protection is required when there is a potential for the splashing, spraying, or splattering of blood or other potentially infectious materials. A mask and eye protection (i.e., goggles or glasses with side shields or chin-length face shield) shall be worn when there is reasonably anticipated exposure to the eyes, nose, or mouth. Prescription glasses may be used as protective eye wear as long as they are equipped with solid side shields that are permanently affixed or are of the "add-on" type. Protective eye wear chosen instead of a face shield shall be worn with a mask to protect the nose and mouth from splashes.

4.0 Responsibilities

All workers and organizations responsible for the safe handling of bloodborne pathogens shall refer to Document 2.1, "Laboratory and ES&H Policies, General Worker Responsibilities, and Integrated Safety Management," in the *ES&H Manual* for a list of general responsibilities. Specific responsibilities are listed below each title.

4.1 Workers

- Conduct each task in accordance with the applicable safety plans
- Follow established procedures.
- Attend required training sessions.
- Participate in the HBV Immunization Program if desired.
- Use PPE and other protective devices when required.
- Report any occupational bloodborne exposure immediately to the Health Services and Hazards Control Departments.
- If you are pregnant, review work activities and procedures with your work supervisor and the Health Services Department.

4.2 Facility Point of Contact

- Know where blood or other potentially infectious materials are used, produced, stored, or handled in any way in the facility.
- Be familiar with this document and its contents and objectives.

4.3 Responsible Individual

- Develop IWS and safety plans (e.g., OSPs, FSPs, and Exposure Control Plans) when work activities involve the use of blood and other potentially infectious materials.
- Approve hazard review forms (or equivalent) and obtain approval from appropriate institutional committees (i.e., Biosafety, Human Subjects, Animal Care and Use). For more information, contact the chair of the respective committee at L-452 or ES&H Teams.
- Be familiar with this document and its application to your operation.
- Plan activities involving the safe use of blood, bodily fluids, or potentially infectious materials.
- Perform ES&H evaluations in coordination with the ES&H Teams.
- Prepare an Exposure Control Plan and emergency, waste disposal, and decontamination plans when needed.
- Provide PPE to workers who work with blood, bodily fluids, or bloodborne pathogens.
- Update the Exposure Control Plan at least annually to reflect changes in worker exposure.
- Notify payroll supervisors of personnel at risk for Hepatitis B.

4.4 Payroll Supervisor

- Assure that workers have applicable information and training before beginning specific tasks involving blood or other potentially infectious materials.
- Determine which workers are required to be offered the HBV Immunization Program and provide a list of these workers to the Health Services Department (L-723) before work begins.

4.5 Health Services Department

- Provide an immunization program for workers who handle blood or other potentially infectious materials.
- Provide medical assessment and treatment of significant exposures and worksite assessment, in collaboration with the Hazards Control Department, to reduce the hazard of subsequent exposures.
- Maintain the medical records of workers who work with blood or other potentially infectious materials, including a record of immunization, surveillance, and post-exposure assessment and treatment.

4.6 Hazards Control Department

- Assist in the identification of hazards associated with blood or other potentially infectious materials.
- Assist workers in working safely with blood or other potentially infectious materials.
- Review hazard assessment forms (or equivalent) for operations involving blood or other potentially infectious materials.
- Determine the need for and frequency of workplace monitoring and inform supervisors, workers, and the Health Services Department of the results.
- Work collaboratively with the Health Services Department in the Post-exposure and Follow-up Programs.
- Provide general training as requested.

4.7 Environmental Protection Department

4.7.1 Environmental Analyst

- Review the hazard review forms (or equivalent) for operations involving the use of blood or other potentially infectious materials.
- Provide guidance to biohazard handlers on how to implement environmental controls and procedures and on the proper management of hazardous waste contaminated with biohazards to ensure compliance with all applicable federal, state, and local environmental requirements.
- Provide specific training to programs and divisions, as required.

4.7.2 Hazardous Waste Management (HWM) Technician

- Provide specific guidance to biohazard handlers on how to properly segregate, package, and label solid and liquid wastes that are contaminated with blood or other potentially infectious materials.
- Coordinate the disposal of waste generated in the area.

5.0 Work Standards

29 CFR 1910.1030 "Bloodborne Pathogens." This standard can be found at the following Internet address:

http://www.osha-slc.gov/OshStd_data/1910_1030.html

National Sanitation Foundation Standard 49: Class II (Laminar Flow) Biohazard Cabinetry, 1992.

Biosafety in the Microbiological and Biomedical Laboratories, 4th edition 1999. U.S. Department of HHS, Public Health Service, HHS Pub No (CDC) 93-8395.

59 FR 34496, "Guidelines for Research Involving Recombinant DNA Molecules," (NIH) July 5, 1994.

64 FR 25361, Guidelines for Research Involving Recombinant DNA Molecules (NIH)," amended May 11, 1999. This standard can be found at the following Internet address:

<http://www.nih.gov/od/oba/>

6.0 Resources for More Information

6.1 LLNL Contacts

For additional information about this document, contact the following as necessary:

- ES&H Teams
- Health Services Department

6.2 Lessons Learned

For Lessons Learned applicable to the topics discussed in this document, refer to the following Internet address:

http://www-r.llnl.gov/es_and_h/lessons/lessons.shtml

6.3 Other Sources

Hunt, D.L., "Human Immunodeficiency Virus Type 1 and Other Bloodborne Pathogens," *Laboratory Safety: Principles and Practices*, 2nd ed, Fleming, Richardson, Tulis, Vesley, Eds. (American Society of Microbiology, 1995) pp. 33–66.

Jahrling, Peter, "Marburg Virus, Ebola Virus, and the Arenaviruses," *Manual of Clinical Microbiology*, 4th ed, Lennette, Balows, Hausler, and Shadomy, Eds. (American Society of Microbiology, 1985) pp. 796–804.

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U.S. Department of Health and Human Services, "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings," *Morbidity and Mortality Weekly Report*, 37(24), (Public Health Service, June 24, 1988).

Occupational Safety and Health Administration, *Interpretation Guide to Occupational Safety and Health Administration Standard*, Subpart 1030, "Interpretation of DOE Security Police Officer," OSHA Instruction CPL 2.58 (October 1, 1983) and CPL 2.59 (November 1983), Record ID# D93043001, p. 2.564.69.

Investigation Report for OSHA Complaint by LLNL Worker, U.S. Department of Energy, Washington, DC, DOE/OAK/LLNL-94-001 (May 31, 1994).

Occupational Safety and Health Administration, *Interpretation Guide to Occupational Safety and Health Administration Standard*, Subpart 1030, "Interpretation of Janitorial Workers," OSHA Instruction CPL 2.58 (October 1, 1983) and CPL 2.59 (November 1983), Record ID# D93043001, p. 2.564.79.

Appendix A

Working Safely in HIV and HBV Research and Production Facilities

The hepatitis B virus (HBV) and the human immunodeficiency virus (HIV) have been classified by the National Institutes of Health (NIH) and Centers for Disease Control (CDC) as Risk Group 2 Agents, which are associated with serious diseases for which preventive and therapeutic interventions are often available ¹. The CDC has recommended Biosafety Level (BL) 2 work practices, containment equipment, and special facilities for all HBV and HIV research activities utilizing known or potentially infectious bodily fluids and tissues. Additional primary containment and personal precautions described in BL3 may be warranted for activities with the potential for droplet and aerosol production and for activities involving production quantities or concentrations of infectious materials.²

All HIV and HBV research and production activities at LLNL that do not have the potential for droplet and aerosol production shall be performed at the BL2 containment level utilizing BL3 work practices in compliance with OSHA standard 29 CFR 1910.1030.

Biosafety Level	BL1	BL2	BL2 Using BL3 Work Practices
A. Hazard Level	Low	Low to Moderate	Moderate to high
B. Standard microbiological techniques			
1. Public access while experiments in progress	Not recommended.	Controlled.	Limited. Doors shall remain closed while work is in progress. Self-closing double door is required for research laboratories.
2. Daily decontamination	Daily, upon spills	Daily, upon spills	Daily, upon finishing work with infectious materials and/or after spills.
3. Infectious waste decontamination	Before disposal	Before disposal	Before disposal ^a
4. Pipetting	Mechanical devices	Mechanical devices	Mechanical devices
5. Eating, drinking, smoking.	Not permitted.	Not permitted.	Not permitted.
6. Handwash/eyewash facility	Required.	Required.	Hand, foot, or automatic operation required for research laboratories.

Biosafety Level	BL1	BL2	BL2 Using BL3 Work Practices
7. Laboratory coats, gowns, smocks, and uniforms.	Required. Not to be worn outside laboratory.	Required. Not to be worn outside laboratory.	Required. Not to be worn outside laboratory.
C. Special practices			
1. Autoclave onsite facility	Not required.	Not required but available with building.	Shall be made available.
2. Insect/Rodent Control Program	Required.	Required.	Required.
3. Transport of infectious material or waste materials for processing (i.e., decontamination) away from the laboratory	Durable, leak- proof, labeled containers	Durable, leak-proof , labeled containers	Waste shall be transported in labeled, durable, leak- proof containers. Decontamination at the site of generation is preferred.
4. Animals not involved with Laboratory Experiments	Not permitted.	Not permitted.	Not permitted.
D. Containment equipment			
1. Biological safety cabinet (BSC) or other containment systems	Required for aerosol-generating processes.	Required for aerosol-generating process.	Required for all work. No bench top work allowed.
2. Miscellaneous physical containment	Equipment shall be decontaminated immediately after use.	Appropriate physical containment devices are used when procedures with a high potential for creating infectious aerosol are being conducted. ^b	Appropriate physical containment devices such as centrifuge safety cups, sealed centrifuge rotors and containment caging for animals are used for all activities with infectious materials that pose a threat of aerosol exposure. ^c
3. Freezers, refrigerators, work areas	Biohazard sign shall be posted.	Biohazard sign shall be posted.	Biohazard sign shall be posted. All BL3 agents shall be stored in separate labeled, closed containers.
4. BSC certification	After installation or relocation and annually thereafter.	After installation or relocation and annually thereafter.	After installation or relocation and annually thereafter.
5. HEPA-filtered vacuum lines	Recommended.	Recommended.	Required HEPA filter and disinfectant.
6. Required BSC decontamination.	After each use.	After each use.	After each use.

Biosafety Level	BL1	BL2	BL2 Using BL3 Work Practices
7. PPE	Gloves shall be worn when handling infected animals and when skin contact with infectious materials is unavoidable.	Gloves shall be worn when handling infected animals and when skin contact with infectious materials is unavoidable.	Required . Appropriate combinations of special protective clothing, masks, gloves, respirators, etc., are used for all activities with infectious materials that may create an aerosol exposure. ^d Molded surgical mask or respirators are worn in rooms containing infected animals.
E. Laboratory facility			
1. Ventilation	Negative pressure	Negative pressure. Open windows require screens.	Negative pressure by ducted exhaust ventilation system is required.
2. Posted hazard sign	Recommended.	Required.	Required posting at all access doors.
3. Bench top work	Permitted.	Permitted.	Not allowed. All work to be performed in BSCs.
4. Open lab window	Permitted with screen.	Permitted with screen.	Permitted with screen.
5. Laboratory separated from general public	No.	Yes.	Yes with limited access.
F. Training			
1. Technical training	Required	Required	Required initially and annually thereafter.
2. Medical surveillance (i.e., baseline serology)	Recommended.	Required when appropriate.	Required when appropriate. HBV vaccine is made available.

^a Destruction of waste shall be performed either by incineration or by a method (e.g., steam sterilization) known to effectively destroy bloodborne pathogens.

^b Procedures include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

^c Procedures include manipulations of cultures and of clinical or environmental materials that may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonic eggs; and necropsies of infected animals.

^d Required with aerosol-generating equipment, manipulation of high concentrations or large volume of infectious materials, and all activities involving clinical specimens, bodily fluids or tissues from human or infected animals or eggs, human cell cultures, or necropsies of infected animals.

References

1. "Guidelines for Research Involving Recombinant DNA Molecules," U.S. Department of Health and Human Services, Public Health Service Centers for Disease Control and National Institutes of Health, Federal Register, Amendment Effective April 29, 1999, Federal Register, May 11, 1999 (64 FR 25361). These guidelines can also be found on the Internet at the following address:

<http://www.nih.gov/od/oba/>
2. *Biosafety in the Microbiological and Biomedical Laboratories*, 3rd ed. (U.S. Department of Health and Human Services, Centers of Disease Control and the National Institutes of Health, Washington, DC, May 1993).
3. "Bloodborne Pathogens" (29 CFR 1910.1030) U.S. Department of Labor—Occupational Safety and Health Administration, Federal Register, Vol. 56. No. 235, December 6, 1991. These guidelines can also be found on the Internet at the following address:

http://www.osha-slc.gov/OshStd_data/1910_1030.html

Appendix B

Precautions and Safe Work Practices for Healthcare Workers

Federal OSHA requires that universal precautions be followed to prevent contact with blood and other potentially infectious materials. The concept of the universal precautions approach is to treat all human blood and certain human bodily fluids as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

The U.S. Department of Health and Human Services Centers for Disease Control has recommended that the system of universal precautions and safe work practices be applied to work activities where there is a moderate to high hazard of occupational exposure to infectious materials.

B.1 Universal Precautions for all Healthcare Providers

The following universal precautions apply to work activities where there is a risk of occupational exposure to infectious materials by healthcare professionals who may have contact with human patients.

1. Use appropriate barriers to prevent skin and mucous membrane exposure when contact with blood or bodily fluids is anticipated.
2. Use gloves if you anticipate touching blood, bodily fluids, mucous membranes, or non-intact skin; when handling items or surfaces contaminated with blood and bodily fluids; and while performing venipuncture and other vascular-access procedures.
3. Change gloves after contact with each patient.
4. Immediately wash your hands upon removing gloves.
5. Use masks, protective eye wear, or face shields during procedures that are likely to generate droplets of blood or other bodily fluids to prevent exposures of the mucous membranes of the mouth, nose, and eyes.
6. Use gowns or aprons during procedures that are likely to generate splashes of blood or other bodily fluids.
7. Immediately and thoroughly wash hands and other skin surfaces with water and an antiseptic cleanser if contaminated with blood or other bodily fluids.
8. Take the necessary precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during or after medical procedures, when cleaning instruments, and during disposal of used needles.

9. To prevent needle-stick injuries, do not recap, bend, break, remove, or otherwise manipulate needles or disposable syringes by hand.
10. After use, place disposable syringes, needles, scalpels, blades, and other sharp items in labeled puncture-resistant containers for disposal. Make sure that these containers are as close as practical to the area where disposable sharps are used.
11. Ensure that mouthpieces, resuscitation bags, or other ventilation devices are available for use where the need for resuscitation procedures is reasonably anticipated.
12. If you have exudative lesions or weeping dermatitis, refrain from handling patients and patient-care equipment until the condition is resolved.

B.2 Safe Work Practices for Healthcare Providers

The safe work practices below are recommended for all Laboratory workers who work with blood or bodily fluids. Workers are not limited to using only these work practices.

B.2.1 Health Care Personnel

1. Follow the universal precautions specified in Section B.1, as applicable.
2. Use gloves and a surgical mask, as appropriate, if you participate in invasive procedures.
3. Use protective eye wear or a face shield for invasive procedures that commonly result in the generation of droplets or the splashing of blood, other bodily fluids, or bone chips.
4. Use gowns or aprons during invasive procedures that are likely to result in the splashing of blood or other bodily fluids.
5. Do not wear torn gloves. Remove and replace them promptly.
6. If a needle stick or other instrument-related injury occurs, remove the needle or instrument involved in the incident from the immediate area.
7. Immediately clean areas that become contaminated with blood or other bodily fluids with a mild solution (1:10 dilution) of household bleach to provide 5,250 ppm of chlorine.
8. Immediately remove regular clothing that becomes contaminated with blood during medical procedures. Keep such clothing separate from other clothing until properly laundered.

B.2.2 Medical and/or Research Laboratory Staff

1. Follow the universal precautions in Section B1, as applicable.
2. Use protective eye wear and a face shield for procedures that commonly result in the generation of droplets or the splashing of blood or other bodily fluids.
3. Use laboratory coats when conducting laboratory procedures and additional protection (e.g., gowns or aprons) when conducting procedures in which the splashing of blood or other bodily fluids can be reasonably anticipated.
4. Use gloves during all procedures that involve the handling of items containing or contaminated with blood or in areas where there may be places (such as benches) that could be contaminated with potentially infectious materials.
5. Do not wear torn gloves. Remove and replace them promptly.
6. Change gloves and wash your hands upon completing specimen processing.
7. Put all specimens of blood and bodily fluids into a well-constructed container with a secure lid to prevent leakage during transport.
8. Exercise care when collecting each specimen to avoid contaminating the outside of the container or the laboratory form accompanying the specimen.
9. Use biological safety cabinets when conducting procedures that have a high potential for generating aerosols.

Note: Biological safety cabinets are not necessary but are recommended for routine procedures such as histological and pathological studies or microbiological culturing.

10. Use mechanical pipetting devices for manipulating all liquids in the laboratory. Mouth pipetting is prohibited.
11. Limit the use of needles and syringes to situations where there are no other alternatives. Pay attention to hand position when using these devices.
12. Decontaminate laboratory work surfaces with an appropriate chemical germicide after a spill of blood or other bodily fluids and upon completing work activities.
13. Clean equipment with a mild solution (1:10 dilution) of household bleach or an appropriate chemical germicide upon completing laboratory procedures. Never store contaminated equipment without the appropriate biohazard label.
14. Wash your hands upon completing laboratory activities. Remove protective clothing before leaving the laboratory.

16. Immediately remove clothing that becomes contaminated with blood or other bodily fluids during collection procedures. Keep such clothing separate from other clothing until properly laundered.

B.2.3 Emergency Medical Providers

1. Follow the universal precautions in Section B.1, as applicable.
2. Use protective eye wear, a mask, or a face shield during emergency medical procedures during which the generation of droplets or the splashing of blood or other bodily fluids is known to occur or can be reasonably anticipated.
3. Use protective, waterproof clothing when handling patients who have experienced extensive trauma or if contact with large quantities of blood is anticipated.
5. Use gloves when handling patients. Promptly remove and replace torn gloves.
6. If a needle stick or other instrument-related injury occurs, remove the needle or instrument involved in the incident from the immediate area.
7. Immediately clean all contaminated equipment with a mild solution (1:10 dilution) of household bleach or an appropriate germicide to provide 5,250 ppm of chlorine.
8. In emergency medical situations involving multiple victims, equipment may become contaminated or potentially contaminated with blood or other bodily fluids of different patients. Do not use contaminated equipment on patients.

Appendix C

Hepatitis B Vaccine

The hepatitis B vaccine (HBV) is a safe and effective vaccine that has been available since 1982. The two different licensed vaccines currently available for use have shown little side effects in clinical trials. The HBV provides over 95% protection against infection nine years or more after vaccination of healthy individuals. The recommended series of three intramuscular doses of vaccine at 0, 1, and 6 months are to be given to induce an adequate antibody response in more than 90% of healthy individuals and in more than 95% of infants, children, and adolescents who are less than 19 years old. Alternatively, the vaccine can be given over a longer period of time (0, 1, 2, and, 12 months) to induce a stronger antibody response. The HBV vaccine is also 70–88% effective when given within 1 week of an HBV exposure. The HBV vaccine, when given with Hepatitis B immune globulin (HBIG), has been found to be over 90% effective in preventing HBV infection following documented exposure.^{1,2}

References

1. Hunt, D.L., "Human Immunodeficiency Virus Type 1 and Other Bloodborne Pathogen," *Laboratory Safety: Principles and Practices*, 2nd ed, Fleming, Richardson, Tulis, Vesley, Eds. (American Society of Microbiology, 1995) pp. 33–66.
2. U.S. Department of Health and Human Services, "Protection Against Viral Hepatitis," *Morbidity and Mortality Weekly Report*, 39(RR-2), (Public Health Service, February 9, 1990). Reprinted February 1992.

Appendix D

HBV, HIV, and HCV in the Workplace

The hepatitis B virus (HBV), also known as "serum hepatitis," has long been recognized as one of many pathogens that causes inflammation of the liver. Other agents that may cause hepatitis include certain drugs, autoimmune diseases, and other infectious agents. An estimated 300,000 Americans, including 8,700 healthcare workers, will acquire this disease in a typical year. An estimated 75,000 (25%) people will develop self-limiting acute hepatitis, and another 18,000–30,000 (6–10%) people will become carriers. An estimated 4,000–6,000 people (1.3–2%) will develop chronic hepatitis and die from cirrhosis or liver cancer (Refs. 1, 2).

The likelihood of becoming infected with HBV from occupational exposure is high. Of persons who have not had prior hepatitis B vaccination or post exposure prophylaxis, approximately 6–30% who are stuck with a needle will become infected. The fatality rate from an HBV infection is 1–2% (Ref. 3).

HIV is the virus that causes autoimmune deficiency syndrome (AIDS) in humans. Epidemiological data indicate that HIV is transmitted through sexual contact, percutaneous or mucous membrane exposure to blood, birth or breast feeding by an infected mother, or transfusion of infected blood.

The transmission of HIV has been determined to be less efficient than the transmission of HBV. As a result, the risk of occupational infection of HIV has been determined to be less than that for HBV. In this country, the likelihood of contracting HIV following a needle- stick exposure from a patient known to be infected with HIV is approximately 0.25% or 2.5 in 1,000 chances. The chances of being infected with both HIV and HBV is 0.3% or 3 in 1,000. Infection depends on various factors, which are discussed in Section 2.0 of this document. The fatality rate from an HIV infection is 100% (Ref. 3).

HIV is very sensitive to changes in temperature and dehydration. Experimental data indicate that a 2 log (99.0%) drop in titer can occur within several hours. In tissue culture fluid, cell-free HIV can be detected for up to 15 days at room temperature (25°C), and up to 11 days at 37°C (Ref. 4).

Hepatitis C Virus, a single stranded envelope RNA virus, is the cause for post transfusion hepatitis. Persons with acute HCV infection typically are either asymptomatic or have a mild clinical illness. Sixty to seventy percent have no discernible symptoms. Twenty to thirty percent might have jaundice. Ten to twenty percent might have nonspecific symptoms (e.g., anorexia, malaise, or abdominal pain).

The course of chronic liver disease is usually insidious, progressing at a slow rate without symptoms or physical signs in the majority of patients during the first two or

more decades after infection. Frequently, chronic hepatitis C is not recognized until asymptomatic persons are identified as HCV-positive during blood-donor screening or elevated Alanine Aminotransferase (ALT) levels are detected during routine physical examinations.

Average time period from exposure to symptom onset is 6 - 7 weeks, whereas the average time period from exposure to seroconversion is 8 - 9 weeks. After acute infection, fifteen to twenty five percent of persons appear to resolve their infection. Most clinical trials of treatment for chronic hepatitis C have been conducted using Alpha-interferon therapy, or combination therapy with interferon and ribavirin, a nucleoside analogue.

References

1. Swenson, P.D., "Hepatitis Viruses," *Manual of Clinical Microbiology*, 5th ed, Balows, Hausler, Herman, Isenberg and Shadomy, Eds. (American Society of Microbiology, 1991) pp. 959-983.
2. U.S. Department of Health and Human Services, "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers," *Morbidity and Mortality Weekly Report*, 38(S-6), (Public Health Services, June 23, 1989). Reprinted February 1992.
3. Hunt, D.L., "Human Immunodeficiency Virus Type 1 and Other Bloodborne Pathogen," *Laboratory Safety: Principles and Practices*, 2nd ed, Fleming, Richardson, Tulis, Vesley, Eds. (American Society of Microbiology, 1995) pp. 33-66.
4. U.S. Department of Health and Human Services, "Recommendations for Prevention of HIV Transmission in Health-Care Settings," *Morbidity and Mortality Weekly Report (Supplement)*, 36(2S), (Public Health Service, August 21, 1987).

Appendix E

Precautions and Safe Work Practices for Law Enforcement Personnel

The safe work practices below are recommended for all Laboratory workers who may have incidental contact with blood or bodily fluids. Workers are not limited to only these work practices, but may also use some of the applicable precautions in Appendix B of this document.

E.1 Protective Service Personnel

1. Use gloves whenever you anticipate touching blood, bodily fluids, mucous membranes, or non-intact skin, or when handling items or surfaces obviously contaminated with blood or bodily fluids.
2. Immediately and thoroughly wash your hands and other skin surfaces with water and an antiseptic cleanser if contaminated with blood or other bodily fluids.
3. Immediately wash your hands after removing gloves.
4. Take the necessary precautions to prevent injuries caused by needles, syringes, and other sharp objects. Pay attention to your hands when handling these items.
5. Make mouthpieces, resuscitation bags, or other ventilation devices available to officers who may be expected to perform cardio-pulmonary resuscitation (CPR).
6. Immediately remove clothing that becomes contaminated with blood or other bodily fluids during operations. Keep such clothing separate from other clothing until properly laundered.
7. Immediately clean areas and equipment that become contaminated with blood or other bodily fluids with a mild solution (1:10 dilution) of household bleach or an appropriate germicide.
8. Attempt to keep the backs of uncooperative individuals towards you to minimize the chances of being bitten. Always try to obtain additional assistance whenever handling an uncooperative individual.

Appendix F

Precautions and Safe Work Practices for Waste Disposal Workers

Waste disposal workers and glass-washing workers are examples of workers whose job may pose no or low risk to exposures. The safe work practices that follow apply to the general duties of these workers. Work practices that shall be implemented for specific situations may not be represented. All waste shall be handled as medical waste and disposed of in accordance with local, state, and federal medical waste regulations. For more information, see Document 36.1, "Waste Management Requirements," in the *ES&H Manual*.

Waste Disposal Workers

1. Use gloves whenever you anticipate touching waste, waste containers marked with a biohazard symbol, or waste from medical or biotechnology facilities, or when handling items or surfaces grossly contaminated with blood and bodily fluids.
2. Immediately and thoroughly wash your hands and other skin surfaces with water and an antiseptic cleanser if contaminated with blood or other bodily fluids.
3. Immediately wash your hands upon removing gloves.
4. Wear eye protection when handling waste containers.
5. Take the necessary precautions to prevent injuries caused by needles, syringes, and other sharp objects.
6. Immediately remove clothing that becomes contaminated with blood or other bodily fluids while performing normal activities. Keep such clothing separate from other clothing until properly laundered.
7. Immediately clean areas or equipment that becomes contaminated with blood or other bodily fluids with a mild solution (1:10 dilution) of household bleach.

Appendix G

Terms and Definitions

Biohazardous materials	Materials that are not capable of self replication and that are the components of biological agents that present a real or potential risk of causing illness or injury to humans, plants, or animals.
Biohazard	Any biological material, or a component thereof, that presents a real or potential risk of illness or injury to humans, plants, or animals.
Biological safety cabinet	<p>An apparatus used for the ventilation control of infectious agents or other biologically derived molecules. These cabinets are divided into three classes by design and containment and cleanliness capability:</p> <p>Class I cabinets, which are most suitable for Safety Level 1 and some Safety Level 2 and 3 containment, are similar to a conventional laboratory hood having an open-face, negative-pressure design.</p> <p>Class II (i.e., laminar-flow) cabinets utilize a HEPA filter in an overhead diffuser to reduce contamination in the cabinet, and are effective in protecting operators from research materials and in protecting research materials from external contamination.</p> <p>Class III cabinets are hermetically sealed enclosures for the handling of extremely hazardous materials at Safety Level 4.</p>
Blood	Human blood, human blood components, and products made from human blood.
Bloodborne pathogens	Pathogenic microorganisms that are present in human blood and that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
CDC	The Centers for Disease Control and Prevention. Agencies of the Public Health Service.

Contaminated	The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
Decontamination	The use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
Engineered controls	Controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove a pathogen hazard from the workplace.
HBV	Hepatitis B virus.
HCV	Hepatitis C virus.
NIH	National Institutes of Health, an agency of the Public Health Service.
Occupational exposure	Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of a worker's duties.
Other potentially infectious materials	<p>Human bodily fluids, (e.g., semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid that is visibly contaminated with blood; and all bodily fluids in situations where it is difficult or impossible to differentiate between bodily fluids.</p> <p>Any unfixed tissue or organ (other than intact skin) from a human (living or dead).</p> <p>HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV, HBV or other human pathogens.</p>
Pathogen	Any agent (usually living) capable of producing disease.

Personal protective equipment	Specialized clothing or equipment worn by a worker for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
Production facility	A facility engaged in industrial-scale, large-volume or high-concentration production of microorganisms.
Regulated biohazardous waste	Liquid or semi-liquid blood or other potentially infectious materials or contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed. Includes items that are caked with dried blood or other potentially infectious materials and which are capable of releasing these materials during the handling of contaminated sharps, pathological waste, or microbiological wastes containing blood or other potentially infectious materials.
Research laboratory	A laboratory producing or using research-laboratory-scale amounts of biological materials or chemicals.
Sharps	Any objects that can penetrate the skin, including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed metal edges such as dental wires.
Universal precautions	An approach to infection control in which all human blood and certain human bodily fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.
Worker	An individual employed in a workplace.
Work practice controls	Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting the recapping of needles by a two-handed technique).